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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

*In re Application of*

**Applicants:** SHANKS, Steven C. and TUCEK, Kevin B.

**Title of Invention:** Multi-Probe Device

**Filed:** July 1, 2003

**Serial Number:** 10/612,504

**Atty Docket No.:** 206-038

**Examiner:** Henry M. Johnson, III

**Art Unit:** 3739

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Sandra L. Etherton

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APPEAL BRIEF

Mail Stop Appeal Brief  
Commissioner of Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

A Notice of Appeal was filed May 2, 2006 which subsequently requires an appeal brief to be filed within two months. This Appeal Brief is submitted within three months of the Notice of Appeal and Applicants petition for a one-month extension. A charge form for the appeal fee of \$250 and the extension fee of \$60 accompanies this brief.

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## Cases Cited



*In re Fulton*, 391 F. 3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004)

*In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

*In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983)

*Hansgird v. Kemmer*, 40 USPQ 665 (CCPA 1939)

*In re King*, 231 USPQ 136 (Fed. Cir. 1986)

*In re Oelrich and Divigard*, 212 USPQ 323 (CCPA 1981)

*In re Ratti*, 123 USPQ 349 (CCPA 1959)


*In re Rijckaert*, 28 USPQ2nd 1955 (Fed. Cir. 1993)

*In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998)

*MEHL/Biophile Int'l Corp. v. Milgraum*, 52 USPQ2d 1303 (Fed. Cir. 1999)

*Verdegaal Brothers, Inc. v. Union Oil Company of California*, 2 USPQ2d 1051 (Fed. Cir. 1987)

## List of References



- R-1** Applicants' Specification and Drawings of U.S. Patent Application No. 10/612,504, as amended (referred to herein as the "Pending App.")
- R-2** U.S. Patent 6,074,411 issued to Lai (referred to herein as "Lai")
- R-3** U.S. Patent 6,267,779 issued to Gerdes (referred to herein as "Gerdes")
- R-4** Office action dated November 10, 2005

*Copies of the references above are included in the References Cited Appendix*

Manual of Patent Examining Procedure, Eighth Edition, August 2001, Rev. 4 October 2005

MPEP §2112.02

MPEP §2142

MPEP §2143.01

MPEP §2146

**I. Real Party in Interest**

The real parties in interest are the inventors, Steven C. Shanks and Kevin B. Tucek.

Appellants note that, in the event a terminal disclaimer is required to avoid a double-patenting type obviousness rejection, upon a notice of allowance and assuming such terminal disclaimer is still required, Applicants will file a terminal disclaimer and an assignment fully complying with 37 CFR § 1.321 and 37 CFR § 3.73. In such case, the real parties in interest will include Erchonia Patent Holdings, LLC, owned in the majority by the inventors.



## II. Related Appeals and Interferences

No appeals or interferences are pending which may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal, however the following are, or were, copending patent applications or litigation related to the application on appeal:

Type	Application or Patent Number	How Related to Application on Appeal	Atty Docket Number
US Patent	6,605,079	this patent claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-001
US Patent	09/932,907 now U.S. Pat. No 6,746,473	this application claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-002
PCT Application	PCT/US2002/019359	PCT application, and national stage applications and issued patents therefrom, claim the benefit of the common priority application US Pat. Application No. 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of common priority application U.S. Provisional Application No. 60/273,282	206-021
CIP of related application	10/772,973	this application claims the benefit of common priority application U.S. Application No. 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-024
CIP of related application	10/772,738	this patent application claims the benefit of common priority application U.S. Application No.	206-032

		09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	
judicial proceeding in Federal District Court of Colorado*	04-MK-1769 (CBS)	litigation alleging infringement of U.S. Pat. No 6,746,473 and invalidity thereof, et alia. U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-066
CIP of Patent Application on appeal	11/443980	this application claims the benefit of the application on appeal, which claims benefit of the common priority application 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-071
DIV of Patent Application on appeal	11/431257	this application claims the benefit of the application on appeal, which claims benefit of the common priority application 09/932,907, now U.S. Pat. No 6,746,473, which claims the benefit of U.S. Provisional Application No. 60/273,282	206-133

\* A Markman hearing was held in Colorado District Court action 04-MK-1769 (CBS) to construe certain claims of U.S Patent No. 6,746,473, which claims the benefit of common priority application 09/932,907, now U.S. Pat. No. 6,746,473. That decision is attached in the Related Proceedings Appendix as Appendix RP-1. No other decisions have been rendered by a court or the Board in any proceeding identified under this section.

**III. Status of the Claims**

Claims 1-10, 13-30, and 32 of U.S. Patent Application No. 10/612,504 are pending and stand rejected twice and constitute the subject matter of this appeal. Claims 11-12, 31, 33 -34 have been cancelled. Claims 35-39 were withdrawn by the Examiner.

**IV. Status of Amendments**

Applicant proposed amendments subsequent to the final office action dated November 10, 2005. Those amendments were considered, but not entered, by the Examiner.

Claim amendments made in response to an office action dated June 3, 2005 were entered by the Examiner in an office action dated November 10, 2005. Those amended claims constitute the subject matter of this appeal and appear in the Claims Appendix as Appendix A.

**V. Summary of Claimed Subject Matter**

In U.S. Patent Application No. 10/612,504, the Applicants present a single laser device that enables a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. paragraphs [0005], [0006], [0007] and [0024] and Fig. 7. This is an improvement over prior art because earlier devices could not freely treat different areas of a patient at the same time.

The claimed device also enables a practitioner to personally and freely treat a patient using multiple laser beam emissions each with a specific spot shape, such as a line. Pending App. paragraphs [0018], lines 1-3. This has the advantage of enabling the practitioner to more precisely define the surface area the laser impinges upon. A copy of Applicants' specification, as amended, and drawings are enclosed for easy reference as Appendix R-1. The claims on appeal are listed in the Claims Appendix.

**A. Independent Claim 1**

Claim 1 defines a device (Pending App. paragraph [0015], line 1) having two or more handheld probes (Pending App. paragraph [0015], line 4). Each of the probes houses one or more laser energy sources (Pending App. paragraph [0016], lines 1-3) and each laser energy source produces a laser beam that is shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph 0017, lines 1-3). Each probe is moved freely by the user while the laser beams are being emitted (Pending App. paragraphs [0015] and [0024]; Fig. 7).

**B. Independent Claim 23**

Claim 23 generally defines the same device as claim 1, except that it specifies that the laser energy sources must be semiconductor laser diodes and adds a control circuit for controlling the laser beams. Specifically, Claim 23 covers a laser device (Pending App. paragraph [0015], line 1) having first and second handheld probes (Pending App. paragraph [0015], line 4). Each of the probes has a semiconductor diode (Pending App. paragraph [0022], lines 3-7) laser energy source (Pending App. paragraph [0016], lines 1-3), and each laser energy source produces a laser beam that is shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph [0017], lines 1-3). There is a control circuit for independently controlling each of the laser beams (Pending App. paragraph [0020], lines 1-9). Each probe is freely moved by the user's hand relative to the surface of the skin of a patient while emitting the first laser beam (Pending App. Paragraphs [0015] and [0024]; Fig. 7).

**C. Independent Claim 30**

Claim 30 generally defines the same device as claim 1 except that it specifies that each laser beam emits a different wavelength of visible light. Specifically, Claim 30 covers a device having two or more laser energy sources (Pending App. paragraph [0016], lines 1-3) housed in two or more handheld probes (Pending App. paragraph [0015], line 4). Each laser beam emits a visible wavelength (Pending App. paragraph [0022], lines 2-8) shown through an optical arrangement to produce a desired spot shape (Pending App. paragraph [0017], lines 1-3). Each probe can be moved freely by the user while the laser beams are being emitted (Pending App. Paragraphs [0015] and [0024]; Fig. 7).

None of the claims on appeal recite means-plus-function limitations.

**VII. Argument**

**A. Lai Does Not Anticipate Applicants' Claims under 35 USC 102(b)**

***Legal Standard for Anticipation***

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers, Inc. v. Union Oil Company of California*, 2 USPQ2d 1051 (Fed. Cir. 1987). Under the principles of inherency, if the prior art in its normal and usual operation would necessarily perform the method claimed, then the method claimed will be considered to be anticipated. MPEP §2112.02. *See MEHL/Biophile Int'l Corp. v. Milgraum*, 52 USPQ2d 1303, 1305 (Fed. Cir. 1999) (citing *In re King*, 231 USPQ 136, 138 (Fed. Cir. 1986)). However, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. MPEP §2112.02 (citing *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich and Divigard*, 212 USPQ 323, 326 (CCPA 1981) (citing *Hansgirg v. Kemmer*, 40 USPQ 665 (CCPA 1939)).

Applicants' burden is to prove that that Lai's device would not perform the claimed invention in its normal and usual operation. *See In re King* at 138.

1. Lai Does Not Anticipate Claims 1, 2, 8-10, 13-15, and 22 Because Lai Does Not Disclose Moving Probes While Emitting Laser Beams

Each of Applicants' claims 1, 2, 8-10, 13-15, and 22 claims handheld probes that "emit one or more laser beams ...while being freely moved by a user's hand..."<sup>1</sup>

Lai does not disclose however, that the probes emit one or more laser beams while being freely moved by a user's hand. Instead, Lai discloses how to eliminate having to hold lasers while they are emitting laser beams, thereby allowing the therapist to perform other tasks during treatment. *See* Lai column 1, lines 47-48; column 2, lines 25-30. Indeed all of Lai's claims specifically give the intended use of providing a hands-free laser diode module during laser treatment. *See, e.g.* Lai column 3, lines 32-33 ("without holding said respective diode laser module by a person's hand"); Lai column 4, line 30 ("without holding by a person's hand").

The fact that a practitioner using the Lai device may move the probes while they emit laser light is not sufficient to establish the inherency of that result or characteristic. During normal and usual operation, a person operating Lai's device would not move the probes while they emit laser light. On the contrary, handholding the probes of Lai's device while they emit laser light would defeat the stated purpose of Lai's invention. Therefore, handheld probes that are freely moveable during laser operation are not inherently disclosed by Lai. Accordingly, claims 1, 2, 8-10, 13-15 and 22 are not anticipated by Lai.

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<sup>1</sup> To forestall any confusion about the placement of the "support structure" limitation in claim 1 without a trailing comma and whether Applicants intended laser beams to be moved during treatment, Applicants note that clause (b)(ii) of claim 1 as amended in the RCE dated April 27, 2005, reads "each of the handheld probes emits one or more laser beams while being freely moved by a user's hand relative to the surface of the skin of the patient."



2. Lai Does Not Anticipate Claims 1, 2, 8-10, 13-15, and 22 Because Lai Does Not Disclose a Beam-Shaping Apparatus

Each of Applicants' claims 1, 2, 8-10, 13-15, and 22 claims "an optical arrangement for receiving one or more laser beams and for transforming each of the laser beams into a desired spot shape."

Lai does not expressly or inherently disclose, however, an optical arrangement to transform the beams into a desired spot shape. Instead, Lai discloses only focusing optics. *See* Lai column 2, lines 33-34. Focus is not the same thing as shape. Focus refers to how clear or fuzzy the image is, whereas shape refers to the perimeter geometry of the image as it impinges the patent's skin. *See* Pending App. paragraph [0017]. Focus is defined in optics as "the clear and sharply defined condition of an image" and "the position of a viewed object or the adjustment of an optical device necessary to product a clear image." RANDOM HOUSE UNABRIDGED DICTIONARY 742 (2<sup>nd</sup> ed. 1987) (attached as Exhibit E-1). A device can emit a laser beam that is in or out of focus, and focusing the beam will not change the resultant shape. That is, focusing optics are not inherent in beam shaping optical arrangements. For example, a linear beam has a linear shape, but may be in or out of focus:

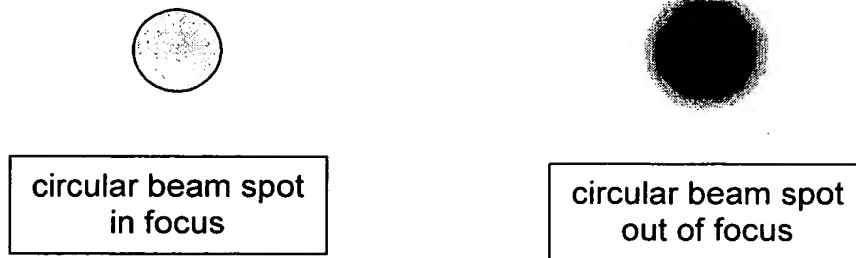


linear beam spot  
in focus

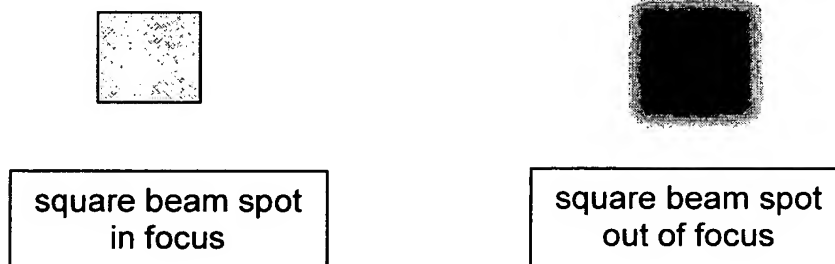


linear beam spot  
out of focus

Similarly a circular beam spot may be in or out of focus:



Similarly a square beam spot may be in or out of focus:



Focusing optics do not necessarily provide an apparatus for obtaining a desired spot shape. Therefore, Lai does not disclose, either expressly or inherently, an optical arrangement for transforming the beam shape, and claims 1, 2, 8-10, 13-15 and 22 are not anticipated by Lai.

3. Lai Does Not Anticipate Claims 1, 2, 8-10, 13-15, and 22 Because Lai Does Not Disclose a Spot Shape

Each of Applicants' claims 1, 2, 8-10, 13-15, and 22 claims "an optical arrangement for receiving one or more laser beams and for transforming each of the laser beams into a desired spot shape."

A spot shape is the result of a beam shape, as explained in Applicants' specification at paragraph [0017]. Lai does not disclose a beam shape, as admitted by the

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Examiner on page 4 of the office action dated November 10, 2005: “Lai et al. is discussed above but does not disclose independent control of the lasers, ultraviolet wavelengths or beam shape.” Instead, Lai discloses only how to focus a beam. However, focus is not the same thing as shape. Focus refers to how clear or fuzzy the image is, whereas shape refers to the perimeter geometry of the image as it impinges the patent’s skin as illustrated in the figures above, which are incorporated into this section by reference. *See also* Pending App. paragraph [0017]. Focus is defined in optics as “the clear and sharply defined condition of an image” and “the position of a viewed object or the adjustment of an optical device necessary to product a clear image.” RANDOM HOUSE DICTIONARY AT 742. A device can emit a laser beam that is in or out of focus, and focusing the beam will not change the underlying shape. That is, a spot shape is not inherent in focusing optics.

Lai does not disclose, either expressly or inherently, a spot shape. Therefore, claims 1, 2, 8-10, 13-15 and 22 are not anticipated by Lai.

4. Lai Does Not Anticipate Claims 30 and 32 Because Lai Does Not Disclose Hand-held Probes While Emitting Laser Beams

Each of Applicants’ claims 30 and 32 claims “...handheld probes for generating two or more laser beams of only visible light ...wherein each of the handheld probes is retained in a hand of a user and freely moved relative to the surface of the skin of a patient.”

Lai does not disclose that the probes emit one or more laser beams while being freely moved by a user’s hand. Instead, Lai discloses how to eliminate having to hold lasers while they are emitting laser beams, thereby allowing the therapist to perform other

tasks during treatment. *See* Lai column 1, lines 47-48; column 2, lines 25-30. Indeed all of Lai's claims specifically give the intended use of providing a hands-free laser diode module during laser treatment. *See e.g.* Lai column 3, lines 32-33 ("without holding said respective diode laser module by a person's hand" Lai column 4, Line 30 ("without holding by person's hand").

The fact that a practitioner using the Lai device may move the probes while they emit laser light is not sufficient to establish the inherency of that result or characteristic. During normal and usual operation, a person operating Lai's device would not move the probes while they emit laser light. On the contrary, handholding the probes of Lai's device while they emit laser light would defeat the stated purpose of Lai's invention. Therefore, handheld probes that are freely moveable during laser application are not inherently disclosed by Lai. Accordingly, claims 30 and 32 are not anticipated by Lai.

5. Lai Does Not Anticipate Claims 30 and 32 Because Lai Does Not Disclose a Beam-Shaping Apparatus

Each of Applicants' claims 30 and 32 claims "an optical arrangement attached to each handheld probe for receiving the laser beams and for transforming each of the laser beams into a desired spot shape.

Again, Lai does not expressly or inherently disclose an optical arrangement to transform the beams into desired spot shape. Instead, Lai discloses only focusing optics. *See* Lai column 2, line 30. Focus is not the same thing as shape. Focus refers to how clear or fuzzy the image is, whereas shape refers to the perimeter geometry of the image as it impinges the patient's skin. *See* Pending App. paragraph [0017]. Focus is defined in optics

as “the clear and sharply defined condition of an image” and “the position of a viewed object or the adjustment of an optical device necessary to product a clear image.”

RANDOM HOUSE DICTIONARY AT 742. A device can emit a laser beam that is in or out of focus, and focusing the beam will not change the resultant shape. That is, an optical arrangement for transforming the beam shape is not inherent in focusing optics.

Lai does not disclose, either expressly or inherently, an optical arrangement for transforming the beam shape. Therefore, claims 30 and 32 are not anticipated by Lai.

6. Lai Does Not Anticipate Claims 30 and 32 Because Lai Does Not Disclose a Spot Shape

Each of Applicants’ claims 30 and 32 claims “an optical arrangement attached to each handheld probe for receiving the laser beams and for transforming each of the laser beams into a desired spot shape.”

Again, a spot shape is the result of a beam shape, as explained in Applicants’ specification. Pending App. at paragraph [0017]. Lai does not disclose a beam shape, however, as admitted by the examiner on page 4 of the office action dated November 10, 2005. Examiner’s quote, *supra* p. 19. Instead, Lai discloses only how to focus a beam. Focus is not the same thing as shape. Focus refers to how clear or fuzzy the image is, whereas shape refers to the perimeter geometry of the image as it impinges the patent’s skin as illustrated by the figures above, which are incorporated into this section by reference. *See also* Applicants’ specification at paragraph [0017]. Focus is defined in optics as “the clear and sharply defined condition of an image” and “the position of a viewed object or the adjustment of an optical device necessary to product a clear image.”

RANDOM HOUSE DICTIONARY AT 742. A device can emit a laser beam that is in or out of focus, and focusing the beam will not change the underlying shape. That is, a spot shape is not inherent in focusing optics.

Lai does not disclose, either expressly or inherently, a spot shape. Therefore, claims 30 and 32 are not anticipated by Lai.

***Conclusion***

Applicants have shown that Claims 1, 2, 8-10, 13-15, 22, 30 and 32 are not anticipated under 35 USC 102(b) by Lai, and reversal of the rejection is respectfully requested.

**B. Applicants' Claims are Not Obvious Under 35 USC 103(a)**

***Legal Standard for Obviousness***

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify the reference or combine the teachings. MPEP §2142; *In re Rouffet*, 149 F.3d 1350, 1356, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998); *In re Geiger* 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). The references must be considered as a whole, and there must be something in the prior art as a whole to suggest the desirability of the combination. MPEP §2142; *In re Fulton*, 391 F.3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004). Moreover, it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). *See also* MPEP §2146; *In re Grasselli*, 218 USPQ 769, 779 (Fed. Cir. 1983); *In re Ratti*, 123 USPQ 349, 352, CCPA 1959.

1. Claims 3-7 and 16-22 are Not Obvious in Light of Lai and Gerdes Because Lai Teaches Against Hand-held Probes

Each of Applicants' claims 3-7 and 16-22 teaches probes that are handheld and freely moved by the user's hand. Although Gerdes teaches hand-held wands, Lai expressly teaches away from hand-held wands. It is well-settled law that it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

The problem solved by Lai is how to relieve a practitioner from having to hold laser probes in his hands. Lai accomplishes this by providing laser diode modules that attach onto a patient's body during treatment using a self-adhesive holder. *See* Lai

column 1, lines 38-39. Lai explains that “[i]t has an adhesive surface and allows to attach a diode laser module onto an acupuncture point of a body part *free of hand-holding*.” Lai column 1, lines 46-48 (emphasis added). “Such holding mechanism is particularly advantageous since it *eliminates the need for hand holding the laser module* and allows the therapist to perform other tasks.” Lai column 2, lines 29-31 (emphasis added). Nowhere in Lai’s disclosure is there any suggestion that handheld wands are desirable. Instead Lai expresses the opposite: the desire is not to have hand-held wands. Therefore, Lai expressly teaches against probes that are handheld. Because it is improper to combine references when one teaches away from the combination, Lai and Gerdes should not be combined, and no *prima facie* case of obviousness has been made.

2. Claims 3-7 and 16-22 are Not Obvious in Light of Lai and Gerdes Because Lai Teaches Against Moving Probes While Emitting Laser Beams

Each of Applicants’ claims 3-7 and 16-22 teaches handheld probes that “emit one or more laser beams ...while being freely moved by a user’s hand...”<sup>22</sup> Lai expressly teaches away from moving the probes while laser beams are being emitted. Again, is well settled that it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

The problem solved by Lai is how to relieve a practitioner from having to hold laser probes in his hands while they are emitting laser beams. Lai explains that:

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<sup>22</sup>To forestall any confusion about the placement of the “support structure” limitation in claim 1 without a trailing comma and whether Applicants intended laser beams to be moved during treatment, Applicants note that clause (b)(ii) of claim 1 as amended in the RCE dated April 27, 2005, reads “each of the handheld probes emits one or more laser beams while being freely moved by a user’s hand relative to the surface of the skin of the patient.”



[S]timulating five to ten acupuncture points are [sic] common and each takes typically five to thirty minutes. Thus, a therapist needs to point the laser beam to one acupuncture point then another for a long time. Obviously, using these devices is inconvenient and is time consuming.

Lai at column 1, lines 27-31. Lai goes on to teach how to eliminate having to hold lasers while they are emitting laser beams, thereby allowing the therapist to perform other tasks during treatment. *See* Lai column 1, lines 47-48; column 2, lines 25-30. Indeed all of Lai's claims specifically give the intended use of providing a hands-free laser diode module during laser treatment. *See e.g.* Lai column 3, lines 32-33 ("without holding said respective diode laser module by a person's hand"; Lai column 4, line 30 ("without holding by a person's hand). To make Lai's device with hand-held lasers would defeat the purpose of Lai's invention and lead to a device that is inoperative under the basic principles under which Lai is designed to operate. Therefore, Lai expressly teaches against probes that are hand-held while emitting laser beams.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, Lai and Gerdes cannot be combined, and no *prima facie* case of obviousness has been made.

3. Claims 3-7 and 16-22 are Not Obvious in Light of Lai and Gerdes Because the Prior Art Teaches Against Freely Moving the Probes

The explicit purpose of Applicants' invention is to enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App. Paragraphs [0006] and [0007]. Each of Applicants' claims 3-7 and 16-22 teach handheld probes that "emit one or more laser beams ...while being freely moved by a user's hand

relative to the surface of the skin of a patient.” Gerdes and Lai each teach away from freely moving the probes, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. *See* Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically, for the laser beams to intersect, the wands must be treating substantially the same area of the patient. It would render Gerdes inoperable to modify it such that the laser beams treated different areas of a patient at the same time because then the laser beams would not intersect. Thus, Gerdes teaches against the probes moving freely.

Lai teaches the use of a self-adhesive holder for each of the diode lasers to attach onto a patient’s body. Lai column 1, lines 38-40. The self-adhesive holder is configured to securely hold the diode laser module and to maintain the laser beam at the acupuncture point. Lai column 2, lines 26-31. It would render Lai inoperable to modify it such that the laser modules moved freely because then they would not be maintained at the acupuncture point.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, and because in this case both prior art references teach away from moving the probes freely, Lai and Gerdes cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.

4. Claim 16 is Not Obvious in Light of Lai and Gerdes Because Neither Lai Nor Gerdes Suggests Using Ultraviolet Laser Light

Applicants' claim 16 claims at least one laser energy source generating a laser beam having a wavelength in the ultraviolet range. Neither Lai nor Gerdes disclose or suggest generating a laser beam having a wavelength in the ultraviolet range.

Lai discloses that the wavelength of the diode laser is selected to have a desirable penetration depth for effectively stimulating an acupuncture point. Lai column 2, lines 43-45. Any wavelength ranged from 500 nm to 1500 nm may be chosen for a variety of acupuncture treatments. Lai column 2, lines 49-51. The range of ultraviolet wavelengths is generally defined as less than 400 nm. Lai does not disclose a wavelength less than 500, and therefore Lai does not disclose ultraviolet wavelengths. The Examiner admits this on page 4 of the final office action dated November 10, 2005 : "Lai et al. is discussed above but does not disclose independent control of the lasers, ultraviolet wavelengths or beam shape." Further, Lai does not indicate that ultraviolet may be used to stimulate an acupuncture point. Therefore, Lai does not suggest using an ultraviolet wavelength.

Gerdes discloses exposing tissue to converging beams of treatment (infrared) radiation having a wavelength of between approximately 900 nm and 1100 nm. Gerdes also discloses aiming (visible) radiation having a wavelength of between approximately 400 nm and 700 nm. Gerdes column 8, lines 53-55; column 9, lines 35-39; column 12, lines 53-60; and all claims. Gerdes does not disclose a wavelength less than 400 nm.

The Examiner alleges on page 5 of the final office action that Gerdes discloses 400 nm of ultraviolet light at column 9, line 38. Gerdes actually refers to

*visible* light at 400 nm, however. Specifically, the Gerdes cite reads in its entirety:

Additionally, each of the *visible* laser radiation sources 170 is also configured to emit radiation having a wavelength preferably between approximately 400 nm to approximately 700 nm, and more preferably between about 635 nm and about 640 nm.

Gerdes at column 9, lines 34-39 (emphasis added). Ultraviolet light is not visible light. Therefore, Gerdes does not suggest an ultraviolet wavelength.

Because each reference affirmatively discloses an operating range and does not disclose operations in the ultraviolet range and because neither the nature of the problem to be solved nor the teachings of Lai suggests the use of ultraviolet wavelengths, neither Lai nor Gerdes suggests using an ultraviolet wavelength. Lacking any suggestion or motivation for an ultraviolet wavelength, no *prima facie* case of obviousness has been made.

5. Claim 17 is Not Obvious in Light of Lai and Gerdes Because Neither Lai Nor Gerdes Suggests a Linear Spot Shape

Applicants' claim 17 requires one of the spot shapes to be substantially linear. Lai does not disclose any beam shape, as the examiner admits on page 4 of the final office action dated November 10, 2005. Examiner's quote, *supra* p. 27. Moreover, while Gerdes discloses that "a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patterns are also suitable for use with the present invention," a line is not a "spread-out" spot shape. Instead, a linear spot shape is the antithesis of "spread-out." See Gerdes column 9, lines 45-49. Lacking any suggestion or motivation of a linear beam shape, no *prima facie* case of obviousness has been made.

6. Claim 19 is Not Obvious in Light of Lai and Gerdes Because Neither Lai Nor Gerdes Suggests a Plus-Sign Spot Shape

Applicants' claim 19 requires one of the spot shapes to be in the shape of a plus sign. Again, Lai does not disclose any beam shape, as the examiner admits on page 4 of the final office action dated November 10, 2005. Examiner's quote, *supra* p. 27. Also again, while Gerdes discloses that "a wide variety of feathered, diffused, Fresnel, traced, and other types of spread-out patterns are also suitable for use with the present invention," a plus sign is not a "spread-out" spot shape. Gerdes at column 9, lines 46-49. Lacking any suggestion or motivation of a plus-sign spot shape, no *prima facie* case of obviousness has been made.

7. Claim 21 is Not Obvious in Light of Lai and Gerdes Because Neither Lai Nor Gerdes Suggests Different Spot Shapes

Applicants' claim 21 requires the spot shape of a first laser beam to be different from a spot shape of a second laser beam; that is, the first and second beam shapes are different. Again, Lai does not disclose any beam shape, as the examiner admits on page 4 of the final office action dated November 10, 2005. *Id.* While Gerdes discloses that a "wide variety" of "spread-out" beam shapes can be used, Gerdes not indicate that the beam shapes emitted from the radiation sources can be different from each other. Lacking any suggestion or motivation of a linear beam shape, no *prima facie* case of obviousness has been made.

8. Claims 23-29 are Not Obvious in Light of Lai and Gerdes Because Lai Teaches Against Handheld Probes

Each of Applicants' claims 23-29 teaches probes that are handheld and freely moved by the user's hand. As explained in section VII (B)(1) above, however, the problem solved by Lai is how to relieve a practitioner from having to hold laser probes in his hands. Lai accomplishes this by providing laser diode modules that attach onto a patient's body during treatment using a self-adhesive holder. *See* Lai column 1, lines 38-39. Lai explains that "[i]t has an adhesive surface and allows to attach a diode laser module onto an acupuncture point of a body part *free of hand-holding*." Lai column 1, lines 46-48 (emphasis added). "The holding mechanism is particularly advantageous since it *eliminates the need for hand holding the laser module* and allows the therapist to perform other tasks. Lai column 2, lines 29-31, emphasis added. Therefore, Lai expressly teaches against probes that are hand-held.

Because it is improper to combine references when one reference teaches away from the combination, Lai and Gerdes cannot be combined, and no *prima facie* case of obviousness has been made.

9. Claims 23-29 are Not Obvious in Light of Lai and Gerdes Because Lai Teaches Against Moving Probes While Emitting Laser Beams

Each of Applicants' claims 23-29 teaches a first handheld probe "from which the first laser beam emits, the first handheld probe ... freely moved by the user's hand relative to the surface of the skin of a patient while emitting the first laser beam."

As explained in section VII (B)(2) above, the problem solved by Lai is how to relieve a practitioner from having to hold laser probes in his hands while they are emitting laser beams. Lai explains that:

[S]timulating five to ten acupuncture points are [sic] common and each takes typically five to thirty minutes. Thus, a therapist needs to point the laser beam to one acupuncture point then another for a long time. Obviously, using these devices is inconvenient and is time consuming.

Lai at column 1, lines 27-31. Lai goes on to teach the laser therapy device art how to eliminate having to hold lasers while they are emitting laser beams, thereby allowing the therapist to perform other tasks during treatment. *See* Lai column 1, lines 47-48; column 2, lines 25-30. Indeed all of Lai's claims specifically give the intended use of providing a laser diode module "without holding said respective diode laser module by a person's hand." *See* Lai column 3, lines 32-33; Lai column 4, lines 30. To make Lai's device with hand-held lasers would defeat the purpose of Lai's invention, and lead to a device that is inoperative under the basic principles under which Lai is designed to operate. Therefore, Lai expressly teaches against probes that are hand-held while emitting laser beams.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose, Lai and Gerdes cannot be combined, and no *prima facie* case of obviousness has been made.

10. Claims 23-29 are Not Obvious in Light of Lai and Gerdes Because the Prior Art Teaches Against Freely Moving the Probes

The explicit purpose of Applicants' invention is to enable a practitioner to personally and freely treat different areas of a patient at the same time. Pending App.

Paragraphs [0006] and [0007]. Each of Applicants' claims 23-29 teach first and second handheld probes that are "freely moved by the user's hand relative to the surface of the skin of a patient while emitting the [first, second] laser beam." Gerdes and Lai each teach away from freely moving the probes, albeit for different reasons. It is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose. *In re Gordon*, 221 USPQ at 1127.

Gerdes teaches a device wherein the wands are positioned over the patient in such a manner that the radiation from the wands intersects within the body being treated. *See* Gerdes column 1, lines 9-12; column 4, lines 45-50 and 56-59. Logically, for the laser beams to intersect, the wands must be treating substantially the same areas of the patient. It would render Gerdes inoperable to modify it such that the laser beams treated different areas of a patient at the same time, because then the laser beams would not intersect. Thus, Gerdes teaches against the probes moving freely.

Lai teaches the use of a self-adhesive holder for each of the diode lasers to attach onto a patient's body. Lai column 1, lines 38-40. The self-adhesive holder is configured to securely hold the diode laser module and to maintain the laser beam at the acupuncture point. Lai column 2, lines 26-31. It would render Lai inoperable to modify it such that the laser modules moved freely because then they would not be maintained at the acupuncture point.

Because it is improper to combine references when one teaches away from the combination or renders the device inoperable for its intended purpose and because in this case, both prior art references teach away from moving the probes freely, Lai and Gerdes cannot be combined. Accordingly, no *prima facie* case of obviousness has been made.



11. Claim 29 is Not Obvious in Light of Lai and Gerdes Because Neither Lai Nor Gerdes Suggests Using Ultraviolet Laser Light

Applicants' claim 29 claims at least one laser energy source generating a laser beam having a wavelength in the ultraviolet range. Neither Lai nor Gerdes disclose or suggest generating a laser beam having a wavelength in the ultraviolet range.

Lai discloses that the wavelength of the diode laser is selected to have a desirable penetration depth for effectively stimulating an acupuncture point. Lai column 2, lines 43-45. Any wavelength ranged from 500 nm to 1500 nm may be chosen for a variety of acupuncture treatments. Lai column 2, lines 49-51. The range of ultraviolet wavelengths is generally defined as less than 400 nm. Lai does not disclose a wavelength less than 500, and therefore Lai does not disclose ultraviolet wavelengths, as the examiner admits on page 4 of the final office action dated November 10, 2005. Examiner's quote, *supra* p. 27. Further, Lai does not indicate that ultraviolet wavelengths may be used to stimulate an acupuncture point. Therefore, Lai does not suggest an ultraviolet wavelength.

Gerdes discloses exposing tissue to converging beams of treatment (infrared) radiation having a wavelength of between approximately 900 nm and 1100 nm. Gerdes also discloses aiming (visible) radiation having a wavelength of between approximately 400 nm and 700 nm. Gerdes column 8, lines 53-55; column 9, lines 35-39; column 12, lines 53-60; and all claims. Gerdes does not disclose a wavelength less than 400 nm.

The Examiner alleges on page 5 of the final office action that Gerdes discloses 400 nm of ultraviolet light at column 9, line 38. Gerdes actually refers to *visible* light at 400 nm however. Specifically, the Gerdes cite reads in its entirety:

Additionally, each of the *visible* laser radiation sources 170 is also configured to emit radiation having a wavelength preferably

between approximately 400 nm to approximately 700 nm, and more preferably between about 635 nm and about 640 nm.

Gerdes column 9, lines 34-39 (emphasis added). Ultraviolet light is not visible light.

Therefore, Gerdes does not suggest an ultraviolet wavelength.

Because each reference affirmatively discloses an operating range and does not disclose operations in the ultraviolet range and because neither the nature of the problem to be solved nor the teachings of Lai suggests the use of ultraviolet wavelengths, neither Lai nor Gerdes suggests using an ultraviolet wavelength. Lacking any suggestion or motivation for an ultraviolet wavelength, no *prima facie* case of obviousness has been made.

### ***Conclusion***

For one or more reasons above, Applicants have shown that Claims 3-7, 16-22, and 23-29 are not obvious under 35 USC 103(a) in light of Lai and Gerdes. Reversal of the rejections is respectfully requested.

**C. Claims 1-10, 13-14, 17, 18, 21, and 23-27 Cannot be Actually Rejected  
for Double-Patenting Because Claims Are Not Yet Otherwise Allowable**

The Examiner has twice actually rejected claims 1-10, 13-14, 17, 18, 21, and 23-27 for being obvious under the non-statutory (judicially-created doctrine of) double patenting as being unpatentable over claims 1-11 and 13 of U.S. Patent 6,746,473 issued to Shanks and Tucek. However, none of these claims has yet been allowed, and therefore no actual double-patenting can be determined. Heretofore Applicant has stated that upon a notice of allowance, and assuming such terminal disclaimer is still required, Applicants will file a terminal disclaimer and an assignment fully complying with 37 CFR § 1.321 and 37 CFR § 3.73.

Applicants have shown that Claims 1-10, 13-14, 17, 18, 21, and 23-27 cannot be actually rejected for double-patenting and reversal of the rejection is respectfully requested.

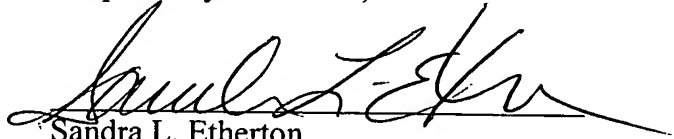
**VIII. Conclusion**

Applicants believe they have shown that none of the Examiner's rejections in the pending application should be sustained. Applicants respectfully request that the Board reverse all the Examiner's rejections and allow the case to proceed to issuance.

Date: \_\_\_\_\_

8/2/06

Respectfully submitted,



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## Claims Appendix

1. A multi-probe device comprising:
  - a) two or more laser energy sources, each generating one or more laser beams;
  - b) two or more handheld probes from which the laser beams emit, wherein:
    - i. each of the handheld probes houses one or more laser energy sources therewithin;
    - ii. each of the handheld probes emits one or more laser beams, and each of the handheld probes is not connected to a support structure while being freely moved by a user's hand relative to the surface of the skin of a patient; and
  - c) an optical arrangement attached to each handheld probe for receiving one or more laser beams and for transforming each of the laser beams into a desired spot shape.
2. A device according to claim 1 wherein at least two of the laser beams are emitted simultaneously and impinge two different parts of a patient's body.
3. A device according to claim 1 further comprising one or more control circuits for independently controlling each of the generated laser beams.

4. A device according to claim 1 further comprising a control circuit for controlling the pulse repetition rate of each laser beam.
5. A device according to claim 4 wherein the pulse repetition rate of at least one of the laser beams is such that the laser light emitted is substantially continuous.
6. A device according to claim 4 further comprising a first laser beam having a first pulse repetition rate and a second laser beam having a second pulse repetition rate wherein the first pulse repetition rate and the second pulse repetition rate are different.
7. A device according to claim 4 further comprising a first laser beam having a first pulse repetition rate and a second laser beam having a second pulse repetition rate wherein the first pulse repetition rate and the second pulse repetition rate are the same.
8. A device according to claim 1 wherein each of the laser energy sources is less than one watt.
9. A device according to claim 1 wherein at least one of the laser energy sources is a semiconductor diode.
10. A device according to claim 1 further comprising a base.

13. A device according to claim 1 wherein at least one laser energy source generates a laser beam having a wavelength in the visible range.
14. A device according to claim 13 wherein the wavelength of the laser beam is in the red range of the visible spectrum.
15. A device according to claim 1 wherein at least one laser energy source generates a laser beam having a wavelength in the infrared range.
16. A device according to claim 1 wherein at least one laser energy source generates a laser beam having a wavelength in the ultraviolet range.
17. A device according to claim 1 wherein at least one of the spot shapes is substantially linear.
18. A device according to claim 1 wherein at least one of the spot shapes is substantially circular.
19. A device according to claim 1 wherein at least one of the spot shapes is substantially in the shape of a plus-sign.

20. A device according to claim 1 wherein at least one of the spot shapes is substantially elliptical.
21. A device according to claim 1 further comprising a first laser beam having a first spot shape and a second laser beam having a second spot shape wherein the first spot shape is different from the second spot shape.
22. A device according to claim 1 further comprising a first laser beam and a second laser beam having the same spot shape.
23. A therapeutic laser device comprising:
  - a) a first semiconductor diode laser energy source generating a first laser beam and a second semiconductor diode laser energy source generating a second laser beam;
  - b) a first handheld probe from which the first laser beam emits, the first handheld probe having an interior cavity that houses the first semiconductor laser energy source therewithin and that is freely moved by the user's hand relative to the surface of the skin of a patient while emitting the first laser beam;
  - c) an optical arrangement mounted in the interior cavity of the first handheld probe for receiving the first laser beam and for transforming the first laser beam into a desired spot shape;



- d) a second handheld probe from which the second laser beam emits, the second handheld probe having an interior cavity that houses the second semiconductor laser energy source therewithin and that is freely moved by the user's hand relative to the surface of the skin of a patient and relative to the first handheld probe while emitting a laser beam;
- e) an optical arrangement mounted in the interior cavity of the second handheld probe for receiving the second laser beam and for transforming the second laser beam into a desired spot shape; and
- f) a control circuit for independently controlling each of the generated laser beams; and
- g) wherein the first and second handheld probes are not connected to a support structure while being freely moved relative to the surface of the skin of a patient.

- 24. A device according to claim 23 further comprising a base.
- 25. A device according to claim 24 wherein the control circuit is housed in the base.
- 26. A device according to claim 23 wherein at least one laser energy source generates a laser beam having a wavelength in the visible range.
- 27. A device according to claim 26 wherein the wavelength of the laser beam is in the red range of the visible spectrum.

28. A device according to claim 23 wherein at least one laser energy source generates a laser beam having a wavelength in the infrared range.
29. A device according to claim 23 wherein at least one laser energy source generates a laser beam having a wavelength in the ultraviolet range.
30. A multi-probe device comprising:
- a) two or more laser energy sources housed in two or more handheld probes for generating two or more laser beams of only visible light wherein each beam of visible light is emitted at a different wavelength from the other beams of visible light;
  - b) wherein each of the handheld probes is retained in a hand of a user and freely moved relative to the surface of the skin of a patient; and
  - c) an optical arrangement attached to each handheld probe for receiving the laser beams and for transforming each of the laser beams into a desired spot shape.
32. A device according to claim 30 wherein the wavelengths of the laser beams are in the red range of the visible spectrum.

## Evidence Appendix



**Appendix E-1**      Random House Unabridged Dictionary 2<sup>nd</sup> ed., 1987, definition of  
“focus,” meanings 3c and 3d

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# RANDOM HOUSE UNABRIDGED DICTIONARY

Second Edition

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*Dedicated to the memory of  
Jess Stein*

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## Related Proceedings Appendix



**Appendix RP-1** – Order Construing Patent Claim Terms of US Patent 6,746,473.

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLORADO  
Honorable Marcia S. Krieger

Case No. 04-cv-01769-MSK-CBS

A MAJOR DIFFERENCE, INC., a Colorado corporation,

Plaintiff,

v.

ERCHONIA MEDICAL, INC., an Arizona corporation,  
ERCHONIA MEDICAL LASERS, L.L.C., an Arizona limited liability company,  
ERCHONIA PATENT HOLDINGS, L.L.C., an Arizona limited liability company,

Defendants,

and

ERCHONIA PATENT HOLDINGS, L.L.C., an Arizona limited liability company,  
ERCHONIA MEDICAL, INC., an Arizona corporation,

Counterclaimants and Third-Party Plaintiffs,

v.

A MAJOR DIFFERENCE, INC., a Colorado corporation,  
ROBERT E. MORONEY, an individual,  
ROBERT E. MORONEY, L.L.C., a Colorado limited liability company,  
MIKI SMITH, an individual,  
KMS MARKETING, INC., a Colorado corporation,  
STARGATE INTERNATIONAL, INC., a Colorado corporation,

Counterdefendant and Third-Party Defendants.

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**ORDER CONSTRUING PATENT CLAIM TERMS**

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THIS MATTER comes before the Court on the parties'<sup>1</sup> Joint Motion for Construction as

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<sup>1</sup> The Plaintiff and Third-Party Defendants are aligned in this matter. For purposes of this ruling, the Court refers to them as "AMD." The Court refers to the Defendants/Third-Party Plaintiffs as "Erchonia."



a Matter of Law of Disputed Claim Terms of U.S. Patent No. 6,746,473 (**#105**). The Court held an evidentiary hearing on the motion on November 17, 2005. Having considered the motion, the parties' briefs (**#102, #109**), the evidence<sup>2</sup> and arguments presented at the hearing, and the designated portions of the deposition testimony of Mike Robinson, the Court finds and concludes as follows.

### I. Jurisdiction

The Court exercises subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

### II. Issues Presented

Pursuant to *Markman v. Westview Inst., Inc.*, 52 F.3d 967 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996), the parties ask the Court to construe terms in U.S. Patent No. 6,746,473 ("the '473 patent") owned by Erchonia Medical, Inc. The disputed claim terms are as follows, in bold print:

1. A laser device comprising: . . .

c) **an optical arrangement attached to the wand for receiving the laser beams and for transforming each of the laser beams into a desired spot shape. . . .**

7. A device according to claim 1 wherein at least one of the spot shapes is **substantially linear**.

8. A device according to claim 1 further comprising a first laser beam having a first spot shape and a second laser beam having a second spot shape wherein the first spot shape is **substantially**

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<sup>2</sup> At the hearing, the Court received Exhibits 1 through 18 on the condition that they would not be admitted unless referred to during the testimony or argument. Of these, all but Exhibits 8, 14, 15 and 17 were referred to during the testimony or argument. Therefore, the Court admits Exhibits 1 through 7, 9 through 13, 16 and 18.

**linear** and the second spot shape is circular. . . .

13. A therapeutic laser device comprising: . . .

c) **an optical arrangement** mounted in the interior cavity of the wand for receiving the laser beams and for **transforming each of the laser beams into a desired spot shape** wherein the first laser beam's spot shape is **substantially linear** and the second laser beam's spot shape is substantially circular; . . . .

The construction of a patent claim presents a question of law. *See Markman*, 517 U.S. at 372. A court's task is to determine what a person of ordinary skill in the relevant art would understand the disputed claim terms to mean as of the effective filing date of the patent application. *See Vanderlande Industries Nederland BV v. Int'l Trade Commission*, 366 F.3d 1311, 1318 (Fed. Cir. 2004); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005), *petition for cert. filed*, 74 USLW 3308 (Nov. 9, 2005) (No. 05-602). A court construes the claims without regard to the device which is alleged to infringe the patent. *See Young Dental Mfg. Co., Inc. v. Q3 Special Products, Inc.*, 112 F.3d 1137, 1141 (Fed. Cir. 1997); *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002).

A court gives intrinsic evidence – *i.e.*, the claim language, the specification, and the prosecution history before the U.S. Patent and Trademark Office (if in evidence) – primary consideration in determining the legally operative meaning of the claim terms. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The specification is usually “the single best guide to the meaning of a disputed term.” *See id.* However, a court should be cautious not to confine the patent claims to the specific embodiments described in the specification unless it is clear that the patentee intended such embodiments to be co-extensive

with the scope of the patent claims. *See Phillips*, 415 F.3d at 1323. The prosecution history, which generally consists of the record of proceedings before the U.S. Patent and Trademark Office, including prior art cited during examination of the patent, can also have “critical significance.” *See id.* at 1317; *Vitronics Corp.*, 90 F.3d at 1582. The context in which the disputed claim term appears also can be instructive. *See Phillips*, 415 F.3d at 1314.

A court should not consider extrinsic evidence – *i.e.*, expert testimony, inventor testimony, dictionaries, technical treatises, and anything else external to the patent and file history – if the intrinsic evidence resolves any ambiguity in a disputed claim term. *See Vitronics Corp.*, 90 F.3d at 1583-84. However, a court should consider extrinsic evidence when the intrinsic evidence is not sufficient to resolve the ambiguity. *See id.* at 1584. Under no circumstances should a court rely upon extrinsic evidence to vary or contradict the claim language or specification. *See id.*

Extrinsic evidence can also shed light on what the relevant art is, even if such evidence is not used to construe the patent terms. *See Vanderlande Industries Nederland BV*, 366 F.3d at 1318. When the consideration of extrinsic evidence would be improper *vis a vis* construction of the claim, a court may still rely upon technical dictionaries to better understand the underlying technology. *See Vitronics Corp.*, 90 F.3d at 1584 n.6. Common-usage dictionaries (as opposed to technical dictionaries) generally are irrelevant unless a person skilled in the relevant art would understand their definitions to apply. *See Vanderlande Industries Nederland BV*, 366 F.3d at 1318. Reliance upon a common-usage or technical dictionary may also be inappropriate when it defines a term differently than how the patentee would define it. *See Phillips*, 415 F.3d at 1322.

### **III. Analysis**

#### **A. The '473 Patent and Prosecution History**

The '473 patent describes a hand-held "therapeutic laser device" which

can simultaneously provide multiple types of low level laser therapy treatments. The device enables laser light of different pulse widths, different beam shapes and spot sizes to be applied externally to a patient's body. The device includes multiple laser sources. In the preferred embodiment, two semiconductor diode laser sources simultaneously provide two separate laser beams, one laser beam producing a line of continuous red laser light and the other producing a spot of pulsed laser light.

Under "Field of Invention," the '473 patent states: "This invention relates generally to medical devices that employ lasers. More particularly, this invention relates to an improved hand-held laser light generator device."

When the inventors of this device first applied for a patent, the examiners rejected all thirteen claims in the application. The examiners concluded that these claims were anticipated by U.S. Patent 6,267,779 to Gerdes, who disclosed

an apparatus for therapeutic laser treatment that includes handheld wands that each may deliver two wavelengths of laser energy, one in the near infrared range and the other in the visible range from solid state diode lasers. The beams are combined and delivered to the wands which include adjustable optics to focus and shape the beams. The beam shape may be circular or rectangular. Rectangular is interpreted as being substantially linear. . . .

The inventors then submitted an Amendment and Response to First Office Action, which provided:

With respect to amended claims 7, 8, and 13, Gerdes does not anticipate these claims because Gerdes does not disclose the use of a linear beam spot. Applicant respectfully argues that, contrary to the Examiner's assertions, a rectangle of Gerdes' beam shape is

not interpreted as substantially linear in the laser arts. A rectangle has length and width; a line has only length. It is more difficult to create a laser line emission than a comparatively wider rectangle. While arguably a line has the “width” of a single wave of light, because any shape can be described at a microscopic level as being a series of single waves, if the Examiner’s assertion were true, all beams shapes would be equivalent; in essence, a series of waves. . .

The examiners allowed the amended claims.

## **B. The Relevant Art**

AMD contends that the relevant art is laser technology. In contrast, Erchonia contends that the relevant art is optics.

### **Intrinsic Evidence**

The intrinsic evidence supports AMD’s construction. The patented device is a “therapeutic laser device,” not a “therapeutic optical device.” Under “Field of Invention,” the patent states that the invention relates to medical devices that employ lasers. The patent specification and claims refer to an “optical arrangement” but otherwise make no reference to the optical arts. In applying for the ‘473 patent, the inventors referenced the “laser arts” when distinguishing their claims from those in the Gerdes patent. Therefore, the Court finds that based upon the intrinsic evidence, the relevant art is laser technology, rather than optics.

### **Extrinsic Evidence**

Even if the intrinsic evidence did not resolve the issue of the relevant art, the extrinsic evidence supports the same conclusion.

Two experts testified at the hearing regarding the relevant art. Dr. Barbara Soltz, who holds a Ph.D. in physics, testified that the relevant art is laser technology. In contrast, Dr. John

Greivenkamp, Jr., who holds a Ph.D. in optical sciences, testified that the relevant art is geometrical optics and optical system design because the patented device is mainly an optical system which includes a laser.

The patented device contains both laser and optical components. However, the device is primarily a laser device to be used in medical applications. Dr. Soltz, who has applied optics to laser technology since prior to 1983 and has founded one company which develops hand-held laser devices for medical applications, explained the role of optics in the laser arts. She testified that in order for a semiconductor laser diode to be useful, "it must use some kind of optics in order to collect and ultimately focus or to direct the light. So inherent in this technology is the use of optics."

The preferred embodiment of the patented device includes two semiconductor diode laser sources, and Claim 5 of the '473 patent provides that at least one of the laser energy sources must be a semiconductor diode. The device's optical components simply affect the laser beam and resulting spot shape. To construct the device, a person would be required to understand the operation of semiconductor laser diodes and any optical elements used to affect the laser beam. Therefore, the relevant art is laser technology.

### **C. "An Optical Arrangement"**

AMD contends that "an optical arrangement" means "one or more lenses, mirrors, prisms, apertures, beam splitters, filters, diffraction gratings or fiber optic wires." It bases this contention upon the patent specification and testimony from Dr. Barbara Soltz.

In contrast, Erchonia contends that "an optical arrangement" means "one or more optical devices or optical elements." Erchonia bases its interpretation upon the meaning ascribed to such

term in the field of optics, in particular by Dr. Greivenkamp. It also relies upon the patent specification, technical and common-usage dictionaries, and other extrinsic evidence.

### **Intrinsic Evidence**

The Detailed Description of the Invention describes two optical arrangements of the preferred embodiment. The optical arrangement of the linear spot shape “includes a collimating lens and a line generating prism” which “are disposed in serial relation to the laser energy source.” The optical arrangement of the circular spot shape “includes a collimating lens and a beam spot shaping lens” which “are disposed in serial relation to the laser energy source.” Nothing in the specification suggests that these are exclusive optical arrangements. Instead, the specification simply describes the preferred embodiment and states:

[I]t will be understood by those skilled in the art that various changes and modifications may be made, and equivalents may be substituted for elements thereof without departing from the true scope of the invention. Therefore, it is intended that this invention not be limited to the particular embodiment disclosed as the best mode contemplated for carrying out the invention, but that the invention will include all embodiments falling within the scope of the appended claims.

Therefore, the patent specification and claim language do not resolve how “an optical arrangement” should be defined. The prosecution history is also silent on this issue. Therefore, the Court turns to the extrinsic evidence.

### **Extrinsic Evidence**

At the hearing, Dr. Soltz testified that “an optical arrangement is either two or more optical elements” such as “lenses, filters, gratings, apertures, prisms, [and] fiber optics.” She also testified that an optical element could include a mirror or beam splitter.

Dr. Soltz' testimony is consistent with the testimony of Dr. Greivenkamp. He interpreted "optical arrangement" to mean "a collection of optical elements." He testified that "optical elements" can include lenses, prisms, mirrors, filters, gratings, apertures, fiber optic wires, crystals, and nonlinear optical elements. He also testified that a person's finger can become an optical element if placed in front of the laser beam.

Therefore, the Court concludes that an "optical arrangement" means "two or more optical elements." The Court declines to delineate the specific optical elements that might fall within this definition because the patent specification and claims do not limit the device to particular optical elements, and it was apparent to both Dr. Soltz and Dr. Greivenkamp that a wide variety of objects could be used as optical elements.

#### **D. "Attached to the Wand"**

AMD asserts that "attached to the wand" means "directly fastened to the wand." It bases such assertion upon the patent specification, testimony from Dr. Soltz and a common-usage dictionary.

Erchonia asserts that "attached to the wand" means "connected, directly or indirectly, or the wand." It bases its assertion upon a Tenth Circuit decision from 1954, *see Pearl Assur. Co. v. School Dist. No. 1*, 212 F.2d 778, 781 (10th Cir. 1954), an unpublished decision from the District of Delaware, *see Medtronic Vascular, Inc. v. Advanced Cardiovascular Systems, Inc.*, 2005 WL 46553 (D. Del. Jan. 5, 2005), and a common-usage dictionary.

#### **Intrinsic Evidence**

The patent claims and specification do not explain how the wand is attached to any optical arrangement. Claim 13(c) provides that the optical arrangement is "mounted in the



interior cavity of the wand” but does not describe how. The prosecution history also sheds no light on this issue. Therefore, the intrinsic evidence does not completely resolve the meaning of the word “attached.”

### **Extrinsic Evidence**

The caselaw relied upon by Erchonia is not persuasive, because neither case interpreted the term “attachment” in the context of the laser arts. In *Pearl Assur. Co.*, 212 F.2d at 781, the Tenth Circuit concluded that a gymnasium was attached to a high school for purposes of an insurance policy when they were connected by a permanent enclosed passageway, a steam line, a hot water line, an electric power line and a common sewer. *Medtronic* does not interpret any permutation of the word “attach” at all.

Dr. Soltz testified that in the laser arts, “attachment” is a “physical mating” which occurs when there is a fixing, securing, or fastening, and does not conventionally occur when there is an intermediate piece. She testified that “‘attachment’ always means a direct attachment.” She acknowledged that the definition she uses in the laser arts is the same as that found in a common-usage dictionary. Dr. Greivenkamp also testified that a person of ordinary skill in the relevant art would understand the word “attached” in the same manner as a lay person.

Therefore, the Court considers the definition of “attach” set forth in the American Heritage Dictionary. It defines “attach” as “to fasten, secure, or join[.]” According to a person of ordinary skill in the relevant art of laser technology, an attachment must be direct. Therefore, the Court concludes that “attached to the wand” means “fastened, secured, or joined to the wand directly.”

**E. “Transforming Each of the Laser Beams”**

AMD contends that “transforming each of the laser beams” means “changing the appearance or form of the spot shape of the beam emitted by each laser energy source.” It bases this contention upon the claim language, the patent specification, a common-usage dictionary, and the testimony of Dr. Soltz.

Erchonia contends that “transforming each of the laser beams” means “changing the appearance or form of each of the laser beams.” It bases its contention upon a common-usage dictionary.

**Intrinsic Evidence**

Nothing in the claim language, the specification, or the prosecution history defines “transforming each of the laser beams.” Therefore, the Court considers extrinsic evidence on this issue.

**Extrinsic Evidence**

Dr. Soltz testified that in the laser arts, “transforming each of the laser beams” means “to control, to shape, to otherwise transfer this highly divergent beam that is characteristic of a laser diode specifically . . . into a different shape.” She also stated that “transforming” would result in a different shape, appearance and form. She testified that her definition of “transforming” is essentially the definition that would be found in a common-usage dictionary. Dr. Greivenkamp also testified that a person of ordinary skill in the relevant art would understand the word “transforming” in the same manner as a lay person.

Therefore, the Court refers to a common-usage dictionary. The American Heritage Dictionary defines “transform” as “to change markedly the appearance or form of[.]” It also

defines it as “to change the nature, function, or condition of[.]” Of these two definitions, the former is a better fit. Here, various optical elements are used to manipulate the invention’s laser beams to produce various spot shapes. Therefore, “transforming each of the laser beams” means “changing the appearance or form of the laser beams.”

#### **F. “Desired Spot Shape”**

AMD asserts that “desired spot shape” means “a spot shape wanted by the laser device designer.” It bases such assertion upon the patent specification, a common-usage dictionary, and the testimony of Dr. Soltz.

Erchonia asserts that “desired spot shape” means “a spot shape desired by anyone.” It bases its assertion upon the context of the claim language.

#### **Intrinsic Evidence**

There is no language in the patent’s specification or claims which suggests what a “desired spot shape” is. The prosecution history is also silent on this issue. Therefore, the intrinsic evidence does not resolve any ambiguity in the definition of “desired spot shape.”

#### **Extrinsic Evidence**

Dr. Soltz testified that in the laser arts, “desired” means “something that is wanted.” She conceded that her definition of “desired” is essentially the definition that would be found in a common-usage dictionary. Dr. Greivenkamp testified that a person of ordinary skill in the relevant art would understand the word “desired” in the same manner as a lay person. Therefore, the Court looks to the definition of “desired” set forth in a common-usage dictionary.

The American Heritage Dictionary defines “desire” as “to wish or long for; want.” This definition, however, does not resolve “who” must desire the spot shape. Dr. Soltz stated that it

could be the manufacturer, designer, customer, client or anybody else as long as the desire was developed prior to the sale of the product. Steven Shanks, one of the named inventors on the '473 patent, agreed that the "desired spot shape" could be desired by the manufacturer, customer or client. Therefore, the Court concludes that "desired spot shape" means "a spot shape desired by anyone."

#### **G. "Substantially Linear"**

AMD contends that "substantially linear" means "a line having minimal width." In support of such contention, AMD relies upon the prosecution history, the patent specification, and a common-usage dictionary.

Erchonia contends that "substantially linear" means "has the appearance of a length significantly greater than its width." In support of such contention, it relies upon both common-usage and technical dictionaries, as well as the claim language.

#### **Intrinsic Evidence**

The patent claim and specification shed no light on the definition of "substantially linear." However, in applying for the '473 patent, Erchonia explained that a rectangle-shaped laser beam is not "substantially linear" for purposes of the laser arts because a rectangle has length and width, and a line has only length, arguably with the width of a single wave of light. Therefore, the Court finds that "substantially linear" means "a line having minimal width".

#### **Extrinsic Evidence**

The extrinsic evidence is contrary to the patent's prosecution history. Dr. Greivenkamp testified that "substantially linear" means "that a shape has acquired some of the properties of a line." He stated that when the aspect ratio is elongated, for instance, when it is 20 or 30 to 1, it is

substantially linear. He also stated that determining whether something is substantially linear would depend upon the particular observer. He conceded that in formulating this opinion, he did not rely on the patent's prosecution history. Therefore, Court declines to adopt Dr. Greivenkamp's definition.

**IT IS THEREFORE ORDERED** that:

- (1) The Joint Motion for Construction as a Matter of Law of Disputed Claim Terms of U.S. Patent No. 6,746,473 (#105) is **GRANTED**.
- (2) The Court defines the disputed patent claim terms as follows:
  - (a) "Optical arrangement" means "two or more optical elements."
  - (b) "Attached to the wand" means "fastened, secured, or joined to the wand directly."
  - (c) "Transforming each of the laser beams" means "changing the appearance or form of the laser beams."
  - (d) "Desired spot shape" means "a spot shape desired by anyone."
  - (e) "Substantially linear" means "a line having minimal width."

Dated this 12th day of January, 2006

**BY THE COURT:**

A handwritten signature in black ink, reading "Marcia S. Krieger". The signature is written in a cursive, flowing style. Below the signature is a horizontal line.

Marcia S. Krieger  
United States District Judge

## References Cited Appendix



- R-1** Applicants' Specification of U.S. Patent Application No. 10/612,504, as amended, and Drawings (referred to herein as the "Pending App.")
- R-2** U.S. Patent 6,074,411 issued to Lai (referred to herein as "Lai")
- R-3** U.S. Patent 6,267,779 issued to Gerdes (referred to herein as "Gerdes")
- R-4** Office action dated November 10, 2005

TITLE  
Multi-Probe Laser Device

FIELD OF INVENTION

[0001] This invention relates generally to medical devices that employ lasers. More particularly, this invention relates to a laser light generator device that has multiple probes, enabling multiple different treatments to be made simultaneously.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0002] This application claims the benefit of co-pending U.S. Application No. 09/932,907 filed 08/20/2001 which claims the benefit of U.S. Provisional Application No. 60/273,282 filed March 2, 2001.

BACKGROUND

[0003] Low energy laser therapy (LLLT) is used in the treatment of a broad range of conditions. LLLT improves wound healing, reduces edema, and relieves pain of various etiologies, including successful application post-operatively to liposuction to reduce inflammation and pain. LLLT is also used during liposuction procedures to facilitate removal of fat by causing intracellular fat to be released into the interstice. It is also used in the treatment and repair of injured muscles and tendons.

[0004] LLLT utilizes low level laser energy, that is, the treatment has a dose rate that causes no immediate detectable temperature rise of the treated tissue and no macroscopically visible changes in tissue structure. Consequently, the treated and surrounding tissue is not heated and is not damaged. There are a number of variables in laser therapy including the wavelength of the laser beam, the area impinged by the laser beam, laser energy, pulse width, treatment duration and tissue characteristics. The success of each therapy depends on the relationship and combination of these variables. For example, liposuction may be facilitated with one regimen utilizing a given wavelength and treatment duration, whereas pain may be treated with a regimen utilizing a different wavelength and treatment duration, and inflammation a third regimen. Specific devices are known in the art for each type of therapy.

[0005] Often it is desirable to treat a patient for multiple types of problems during a single treatment. Because specific therapies require different regimen, treating multiple problems currently requires multiple separate laser devices. It is desirable to provide a device that enables multiple types of treatments with a single device. It is also desirable to be able to provide multiple treatments simultaneously with a single device, in different areas of a patient's body.

[0006] Therefore, an object of this invention is to provide a laser therapy device that enables multiple types of treatments. It is another object to provide a single device that provides these treatments simultaneously. It is another object of this invention to provide an apparatus that can simultaneously emit multiple beams of laser light that can be applied to multiple areas of a patient's body. It is another object of this invention to provide an apparatus that can simultaneously emit laser light in multiple different pulse widths. It is a further object of this invention to provide an apparatus that can simultaneously emit laser light in multiple beam shapes and spot sizes. It is a particular object of this invention to provide a hand-held therapeutic laser device to provide low level laser therapy which can be used to simultaneously facilitate liposuction, treat post-operative inflammation and pain, and treat and repair injured muscles and tendons.

#### SUMMARY OF THE INVENTION

[0007] This invention is an improved hand-held laser device that can simultaneously provide multiple types of low level laser therapy treatments to multiple areas of a patient's body simultaneously. The device enables laser light of different pulse widths, different beam shapes and spot sizes to be applied to a patient's body. The device includes multiple laser sources. In the preferred embodiment, two semiconductor diode laser sources simultaneously provide two separate laser beams from separate probes, one laser beam producing laser light at a first pulse width and the other producing laser light at a second pulse width.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0008] FIG. 1 is a schematic illustration of a preferred embodiment of the present invention.



[0009] FIG. 2 is a schematic view of the optical arrangement producing a line spot shape of the preferred embodiment.

[0010] FIG. 3 is a schematic view of the optical arrangement producing a circular spot shape of the preferred embodiment.

[0011] FIG 4 is a schematic illustration of a preferred embodiment of the present invention, where the dotted line defines the components disposed in each probe.

[0012] FIG 5 is a schematic illustration of an alternate embodiment of the present invention, where the dotted line defines the components disposed in each probe.

[0013] FIG. 6 is a schematic illustration of an alternate embodiment of the present invention, where the dotted line defines the components disposed in each probe.

[0014] FIG. 7 is a schematic illustration of application of low-level laser radiation using the preferred embodiment of the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

[0015] Referring to the drawings, there is illustrated a hand-held laser device designated generally as 10. The device includes one or more laser energy sources, a power source, at least two optical arrangements, one or more control circuits, and at least two hand-held aiming devices, referred to herein as probes. Fig. 1 shows the preferred embodiment in which a first probe 11 and a second probe 12 are connected to a base 14, which includes a power source 15 (not shown). The base 14 is typically a hand-held unit, but it may also be a stationary unit that typically sits on a table or the ground, functioning as a central base from which many probes may be employed.

[0016] The preferred embodiment comprises a first laser energy source 21 for emitting light from the first probe 11 and a second laser energy source 22 for emitting light from the second probe 12. The laser energy sources 21 and 22 are connected to the power source 15. The power source preferably provides direct current, such as that provided by a battery, but may instead provide alternating current such as that provided by conventional building current which is then converted to direct current. These laser energy sources can be energized independently or simultaneously, which throughout this specification refers to acts occurring at generally at the same time.

[0017] The first laser energy source 21 and second laser energy source 22 each produce a laser beam which exits the laser and is shone through optical arrangements 41 and 42, respectively, that produce beam spots. The beam spot is the cross-sectional shape and size of the emitted beam as it exits the optical arrangement. For example, a laser beam of circular cross-section creates a circular beam spot as the laser light impinges the patient's skin. If the laser light emitted is in the visible range, a circular spot can be seen on the patient's skin of substantially the same diameter as the laser beam emitted from the optics arrangement. Various beam spot shapes can be created, including a line, a circle, an ellipse, a plus-sign, or combination of any of them. The probes may product different spot shapes, or have the same spot shapes.

[0018] In the preferred embodiment, the first laser beam is passed through a first optical arrangement that generates a beam of substantially linear cross-section, resulting in a line of laser light seen on the patient's skin. The second laser passes through a second optical arrangement that generates a beam of circular cross-section, resulting in a circular spot shape as seen on the patient's skin. Fig. 2 illustrates the first optical arrangement 41 of the preferred device, which includes a collimating lens 44 and a line generating prism 45. The collimating lens 44 and the line generating prism 45 are disposed in serial relation to the laser energy source 21. The collimating lens 44 and the line generating prism 45 receive and transform the generated beam of laser light into the line of laser light L. As an alternative, a suitable electrical or mechanical arrangement could be substituted for the optical arrangement 41.

[0019] As shown in Fig. 3 the second optical arrangement 42 of the preferred device includes a collimating lens 46 and a beam spot shaping lens 47. As with the first optical arrangement, the collimating lens 46 and beam spot shaping lens 47 are disposed in serial relation to the second laser energy source 22. The collimating lens 46 and beam spot shaping lens 47 receive and transform the generated beam of laser light into a circular beam spot of laser light C. As an alternative, a suitable electrical or mechanical arrangement could be substituted for the optical arrangement 42 to achieve a desired spot shape.

[0020] Control circuitry is connected to the laser energy sources to control whether the lasers are on or off, how long the lasers are powered on, the duration of each pulse of

laser light emitted, and the period of time between one pulse starting and the next pulse starting, referred to herein as the pulse width. Typically the control circuitry is digital, in discrete or integrated circuits, as is known in the art, but analog circuits can also be employed. In the preferred embodiment there are separate control circuits for each probe. Control circuits 31 and 32 are connected to the laser energy sources 21 and 22, respectively, to control the various parameters of the emissions. For ease of reference, pulse widths can be referred to in shorthand notation in cycles/second, or Hz. Pulse widths from 0 to 100,000 Hz may be employed to achieve the desired effect on the patient's tissue. At 100,000 Hz, the pulse width is 0.00001 second. At 0 Hz, a continuous beam of laser light is generated. The goal for LLLT regimen is to deliver laser energy to the target tissue utilizing a pulse width short enough to sufficiently energize the targeted tissue and avoid thermal damage to adjacent tissue.

[00021] The probes have an interior cavity. In the preferred embodiment, the first laser energy source 21 and first optical arrangement 41 are contained in the first probe 11 and the second laser energy source 22 and second optical arrangement 42 are contained in the second probe 12, while the power source 15 and control circuitry 31 and 32 are contained within the base 14. See Fig. 4, which illustrates the configuration of the components of the invention as they relate to each probe, and where the dotted line 17 indicates the components disposed in the first probe and dotted line 18 indicates the components disposed in the second probe. Alternatively, the laser energy source, optical arrangement, and control circuitry can be housed in the probe. That is, the first laser energy source 21, the first optical arrangement 41, and the control circuitry for the first probe 31 are contained in the first probe 11, and the second laser energy source 22, the second optical arrangement 42, and the control circuitry for the second probe 32 are contained in the second probe 12, as the power source 15 remains within the base 14. See Fig. 5 in which dotted lines 17 and 18 again indicate the components that are in the probes. Fig. 6 shows another alternate configuration, in which a single laser energy source 23, a single control circuitry 33 for the first probe and the second probe, and the power source 15 are contained in the base 14, and the probes contain only the optical arrangement for the first probe 41 and the optical arrangement for the second probe 42,

respectively. Again, the dotted lines 17 and 18 indicate which components are in the probes.

[0022] Laser energy sources are known in the art for use in low-level laser therapy. Visible light in about the 400-700 nm range is preferred, and the frequency is determined by the particular therapy given to the patient. The laser energy sources include Helium-Neon lasers having a 632 nm wavelength and semiconductor diode lasers with a broad range of wavelengths between about 600-800 nm. The laser energy sources in the preferred embodiment are two semiconductor laser diodes that produce light in the red range of the visible spectrum, having a wavelength of about 635 nm. Other suitable wavelengths are used for other particular applications. While many LLLT regimen include visible laser light, it may be advantageous to utilize ultraviolet (approx. 1-400 nm) or infrared (approx 700 – 10<sup>5</sup> nm) laser energy, again depending on the type of treatment desired. Solid state and tunable semiconductor laser diodes may also be employed to achieve the desired wavelength.

[0023] Different therapy regimens require diodes of different wattages. The preferred laser diodes use less than one watt of power each to simultaneously facilitate liposuction, treat post-operative inflammation, and post-operative pain. Diodes of various other wattages may also be employed to achieve the desired laser energy for the given regimen.

[0024] Fig. 7 illustrates the device in use. A practitioner 70 treats one area of the patient 71 with the first probe 11 and treats a different area of the patient 71 with the second probe 12.

[0025] While there has been illustrated and described what is at present considered to be a preferred embodiment of the present invention, it will be understood by those skilled in the art that various changes and modifications may be made, and equivalents may be substituted for elements thereof without departing from the true scope of the invention. Therefore, it is intended that this invention not be limited to the particular embodiment disclosed as the best mode contemplated for carrying out the invention, but that the invention will include all embodiments falling within the scope of the appended claims.

## ABSTRACT

A hand-held laser device that can simultaneously provide multiple types of low level laser therapy treatments to multiple areas of a patient's body simultaneously. The device enables laser light of different pulse widths, different beam shapes and spot sizes to be applied to a patient's body. The device includes multiple laser sources. In the preferred embodiment, two semiconductor diode laser sources simultaneously provide two separate laser beams from separate probes, one laser beam producing laser light at a first pulse width and the other producing laser light at a second pulse width.

**VI. Grounds of Rejection to be Reviewed on Appeal**

- A. Are Claims 1, 2, 8-10, 13-15, 22, 30 and 32 unpatentable under 35 USC 102(b) as being anticipated by U.S. Patent 6,074,411 issued to Lai?**
- B. Are Claims 3-7, 16-22, and 23-29 unpatentable under 35 USC 103(a) as being obvious in light of Lai in view of U.S. Patent 6,267,779 issued to Gerdes?**
- C. Are Claims 1-10, 13-14, 17, 18, 21, and 23-27 unpatentable as double-patenting claims 1-11 and 13 of U.S. Patent 6,746,473 issued to Shanks and Tucek??**



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,504	07/01/2003	Steven C. Shanks	206-038	3500
33354	7590	11/10/2005		
ETHERTON LAW GROUP, LLC 5555 E. VAN BUREN STREET, SUITE 100 PHOENIX, AZ 85008				
			EXAMINER JOHNSON III, HENRY M	
			ART UNIT 3739	PAPER NUMBER

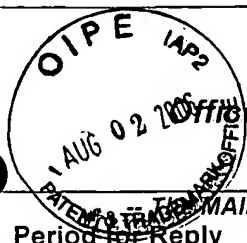
DATE MAILED: 11/10/2005

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Please find below and/or attached an Office communication concerning this application or proceeding.

Appendix R-4

*Ether*



# Office Action Summary

Application No.

10/612,504

Applicant(s)

SHANKS ET AL.

Examiner

Henry M. Johnson, III

Art Unit

3739

MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-30, 32 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) 35-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-30 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 081205.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_



### ***Response to Arguments***

Applicant's arguments filed October 3, 2005, with respect to the rejections of claims 1-7, 9, 10 and 23-25 under Tatebayashi et al. and claims 30 and 32 under Gerdes, have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of U.S. Patent 6,074,411 to Lai.

### ***Election/Restrictions***

Newly submitted claims 35-39 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Surgical methods are classified in 128/898 while light therapeutic devices are classified in 607/89.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 35-39 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Specification***

Full continuation data is required in the first paragraph of the specification; i.e. This application is a continuation-in-part of U.S. Patent Application 09/932,907 filed August 20, 2001, now U.S. Patent 6,746,473 which claims the benefit of U.S. Provisional Application No. 60273,282 51 filed March 2, 2001.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 13-14, 17, 18, 21 and 23-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 13 of U.S. Patent No. 6,746,473. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are an obvious change in scope. A controller is claimed, yet not claimed in the wand, implying the controller is in another component (base).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 8-10, 13-15, 22, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,074,411 to Lai et al. Lai et al. teach a multiple laser diode apparatus for therapy using multiple hand-movable probes (Fig. 1), each with a laser diode with

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a wavelength between 500 and 1500 nanometers operating at about 5 mW (Col. 2, lines 42-45) and the probe is disclosed as having focusing optics (Col. 2, lines 32-35). Focusing optics inherently provide some spot shape.

Regarding claim 2, the destination of the beams is intended use with no further limitation on the device structure.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-7, 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,074,411 to Lai et al. as applied to claim 1 above, and further in view of U.S. Patent 6,267,779 to Gerdes. Lai et al. is discussed above but does not disclose independent control of the lasers, ultraviolet wavelengths or beam shape. Gerdes discloses an apparatus for therapeutic laser treatment that includes handheld wands (Fig. 7) that each may deliver two wavelengths of laser energy, one in the near infrared range and the other in the visible range (Col. 8, line 54) from solid-state diode lasers (Col. 7, lines 22-24). The beams are combined and delivered to the wands that include adjustable optics to focus and shape the beams (Col. 8, lines 31-34). The beam shape may be circular or rectangular (Col. 9, line 49), or a variety of other patterns. A controller for the sources is disclosed that may control the pulse parameters, including, continuous or pulsed, pulse duty cycle and duration of application for each of the radiation sources synchronously or independently with continuous operation possible by selection of a duty cycle of 100 percent (Col. 11, lines 3-8). Specifically mentioned is a pulse frequency of one hertz (Col. 11, line 63). The system is capable of emitting radiation at less

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than one watt; with 0 to 2.0 W specified for the infrared and 0 to 6 mW specified for the visible (Col. 9, lines 14 and 31). The wavelength disclosed for red is 635 nm (col. 9, line 39), for ultraviolet is 400 nm (Col. 9, line 38) and for infrared is 980 nm (Col. 9, line 27). The handheld wands are connected to the radiation sources within the controller cabinet (base) via optical fibers (Col. 8, lines 23-25). Gerdes discloses a mode in which only the two red aiming beams are generated (Col. 11, lines 45-50), after which, a routine is executed to determine if operation of the therapeutic laser is proper. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the control parameters, spot sizes and ultraviolet wavelengths as taught by Gerdes in the invention of Lai et al. to effect a wide range of therapy from the device. Further, all of the variable parameters are well known in the art and would be considered routine to vary in a course of treatment.

Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,074,411 to Lai et al. in view of U.S. Patent 6,267,779 to Gerdes. Both have been previously discussed. Both Lai et al. and Gerdes teach a base unit that houses the control circuits for the lasers. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the control parameters, spot sizes and ultraviolet wavelengths as taught by Gerdes in the invention of Lai et al. to effect a wide range of therapy from the device. Further, all of the variable parameters are well known in the art and would be considered routine to vary in a course of treatment.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

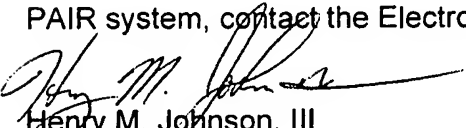
Art Unit: 3739

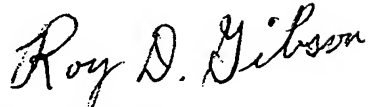
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Henry M. Johnson, III  
Patent Examiner  
Art Unit 3739

  
ROY D. GIBSON  
PRIMARY EXAMINER

PTO/SB/08A (07-05)

Approved for use through 07/31/2006, OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1448/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/812,504
Filing Date	07/01/2003
First Named Inventor	SHANKS, Steven C.
Art Unit	3739
Examiner Name	Henry M. Johnson
Attorney Docket Number	206-038

Sheet 1 of 1

## U. S. PATENT DOCUMENTS

[illegible]

**FOREIGN PATENT DOCUMENTS**

[illegible]

**Examiner  
Signature**

Date  
Conc

11/7/05

**EXAMINER:** Initial reference considered, whether or not citation is in conformance with MPEP 909. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). \*See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \*Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

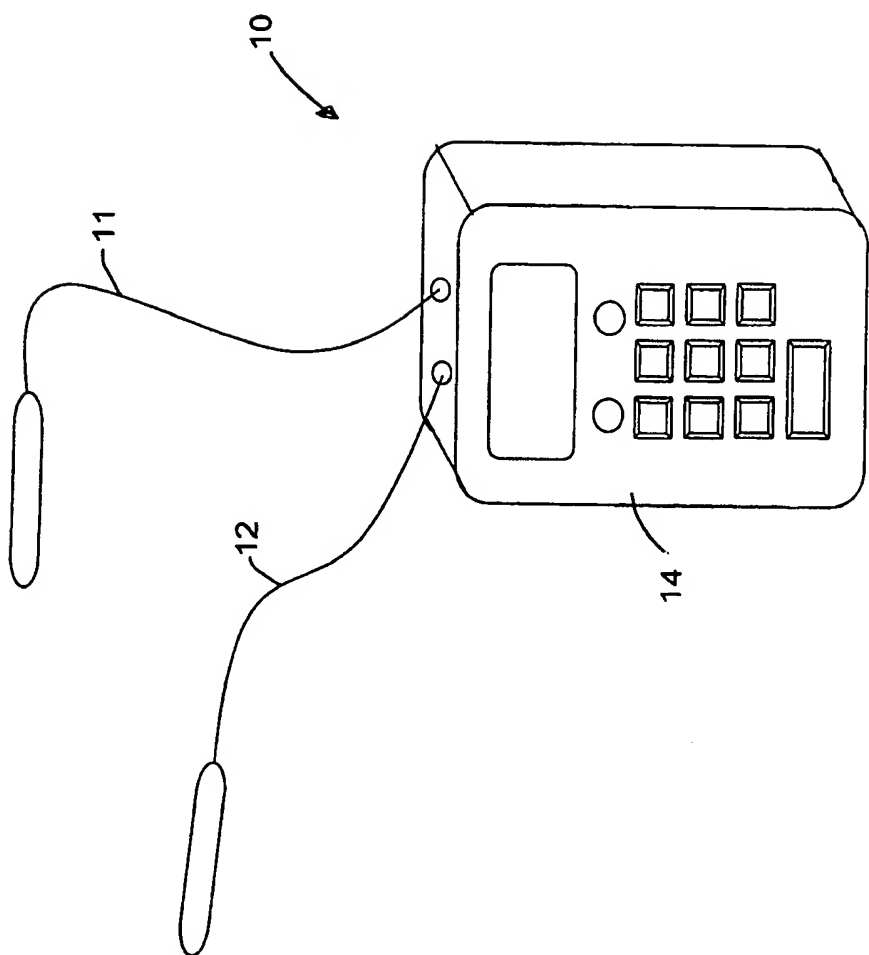


FIG. 1

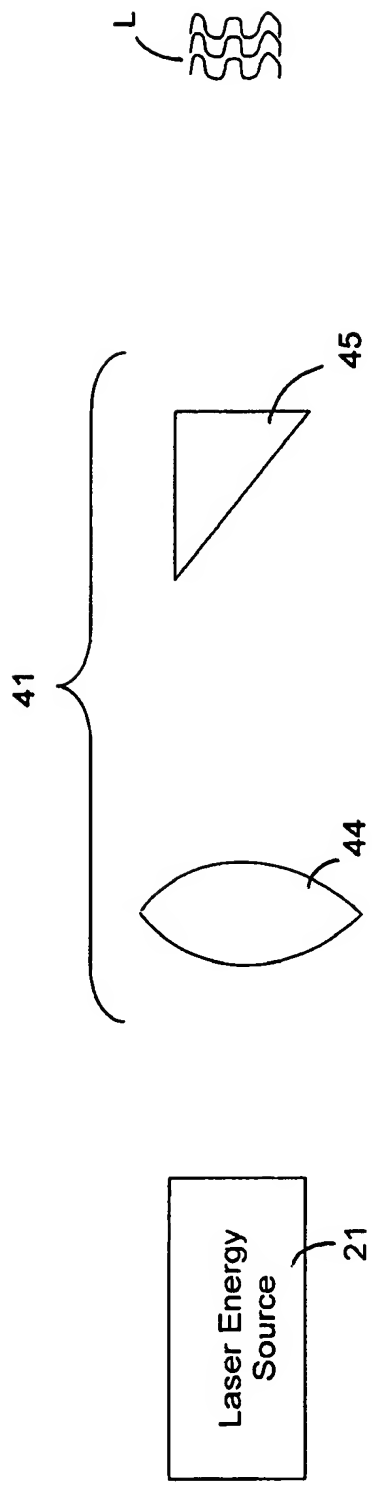


FIG. 2

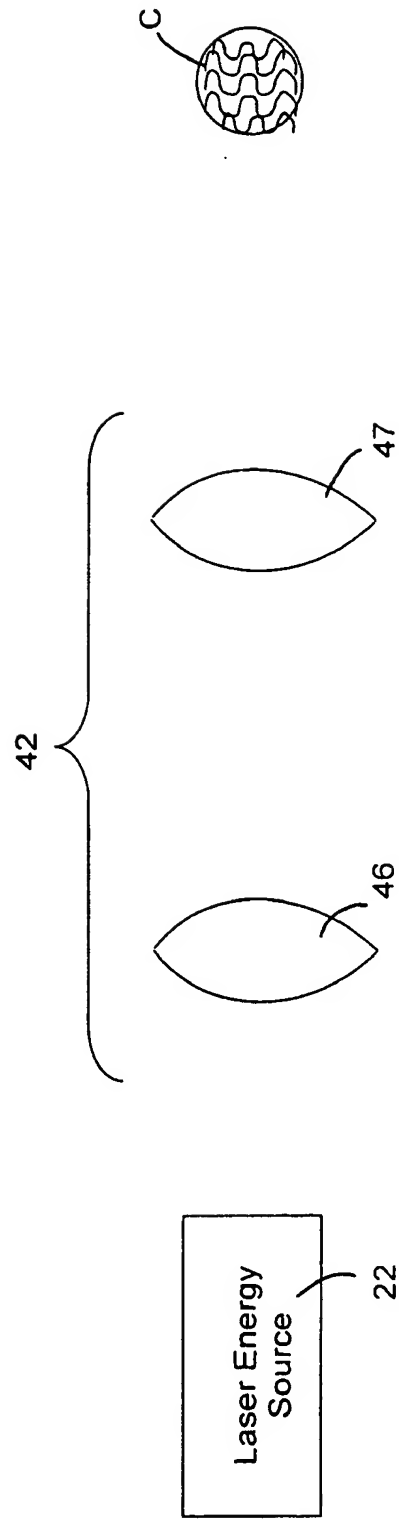


FIG. 3



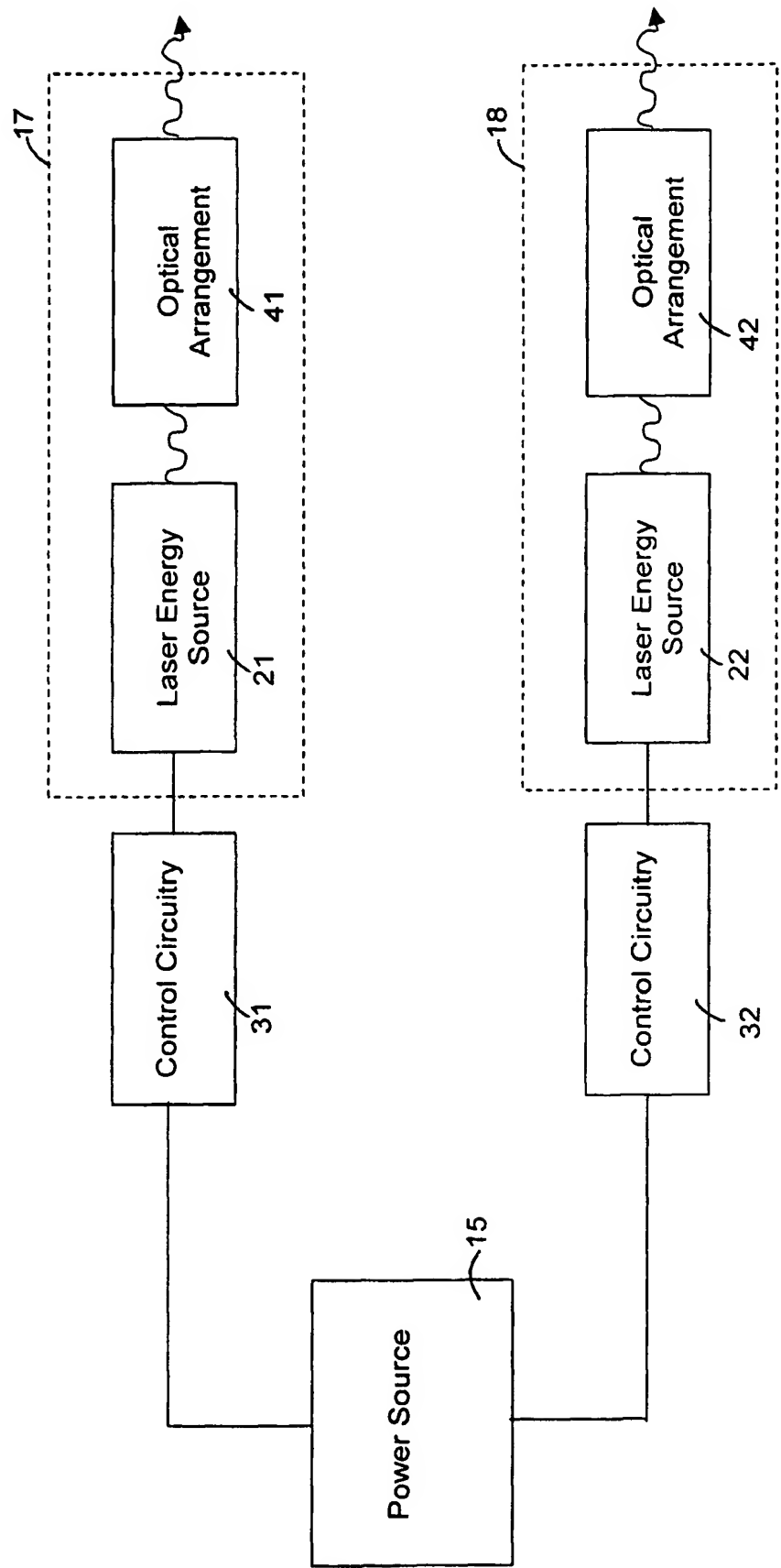


FIG. 4

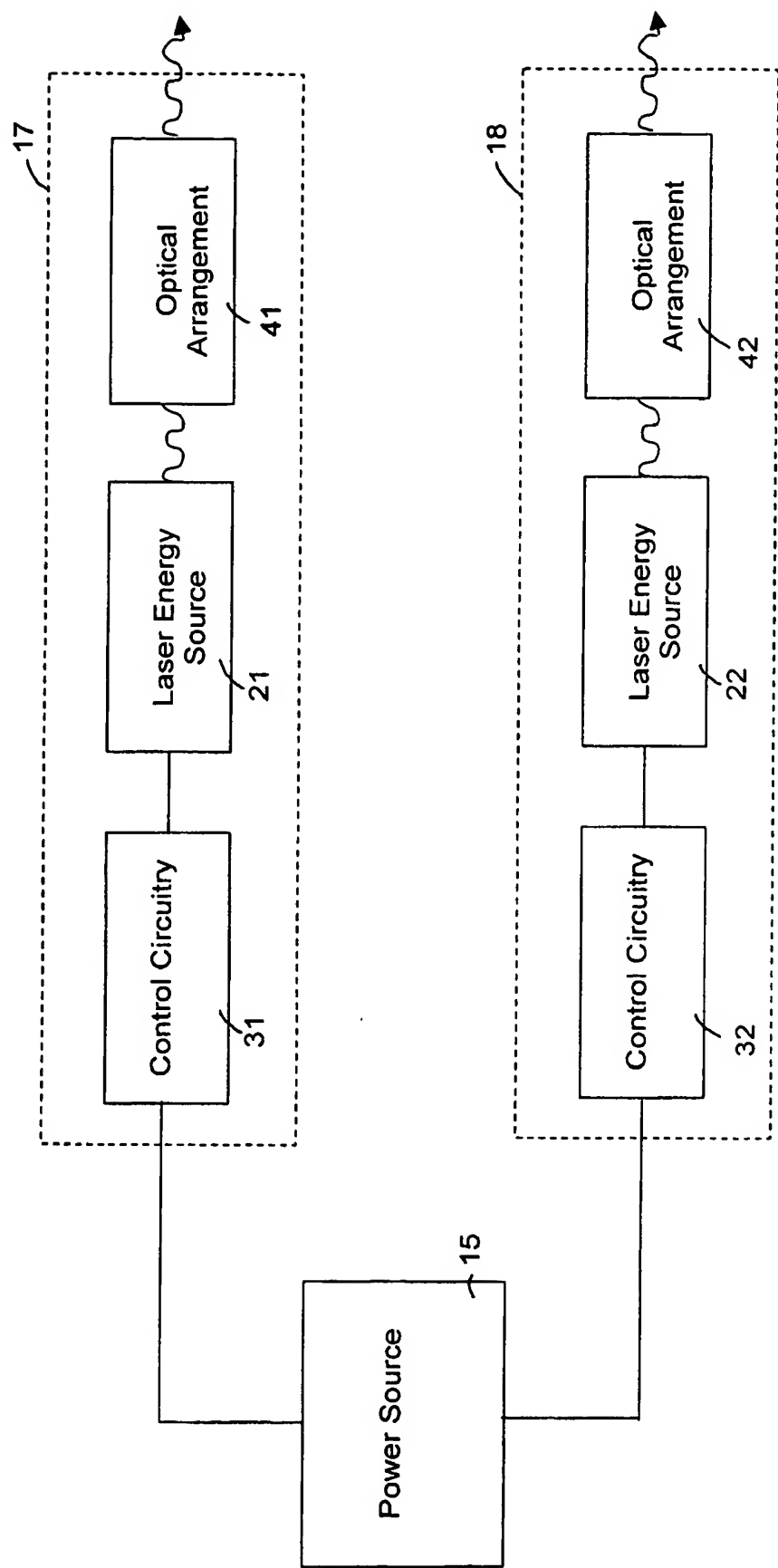


FIG. 5

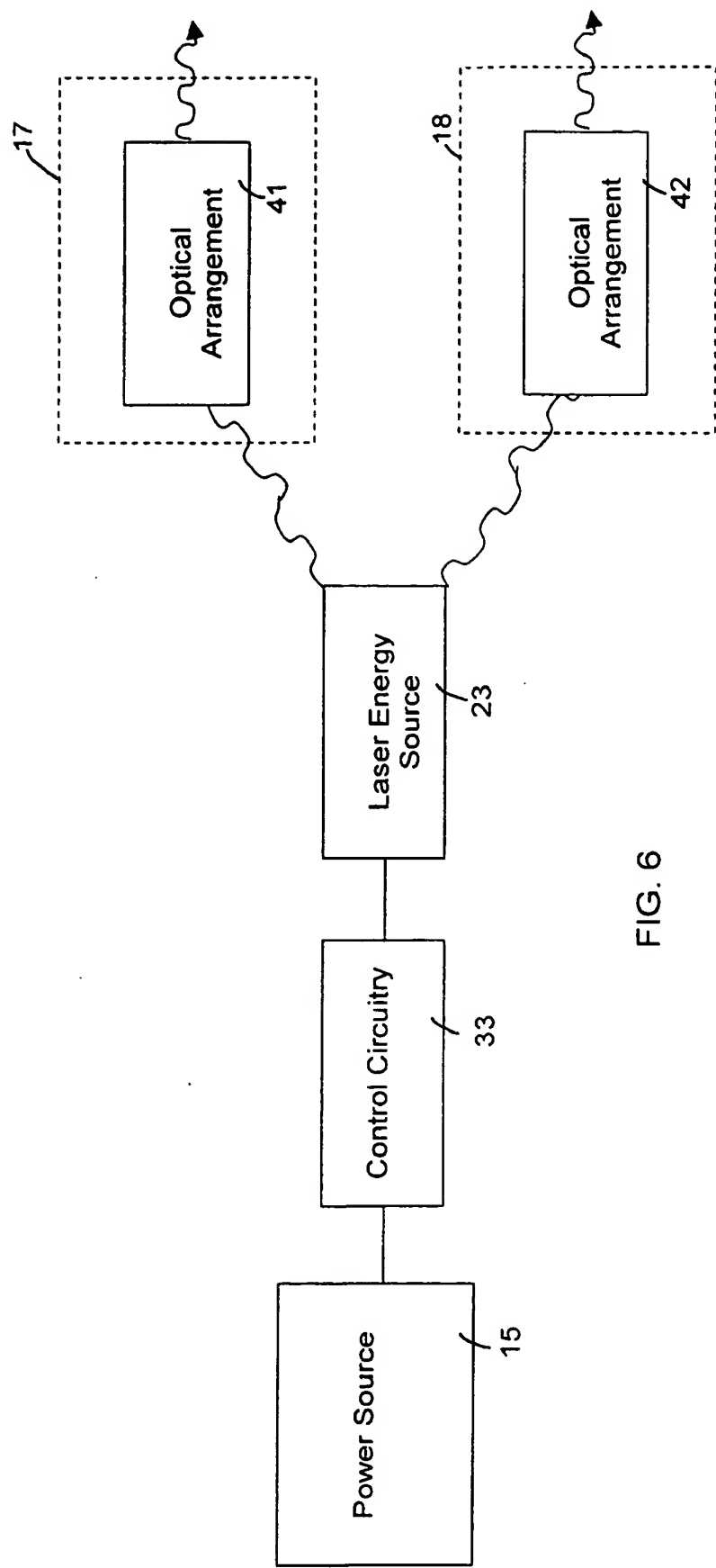


FIG. 6

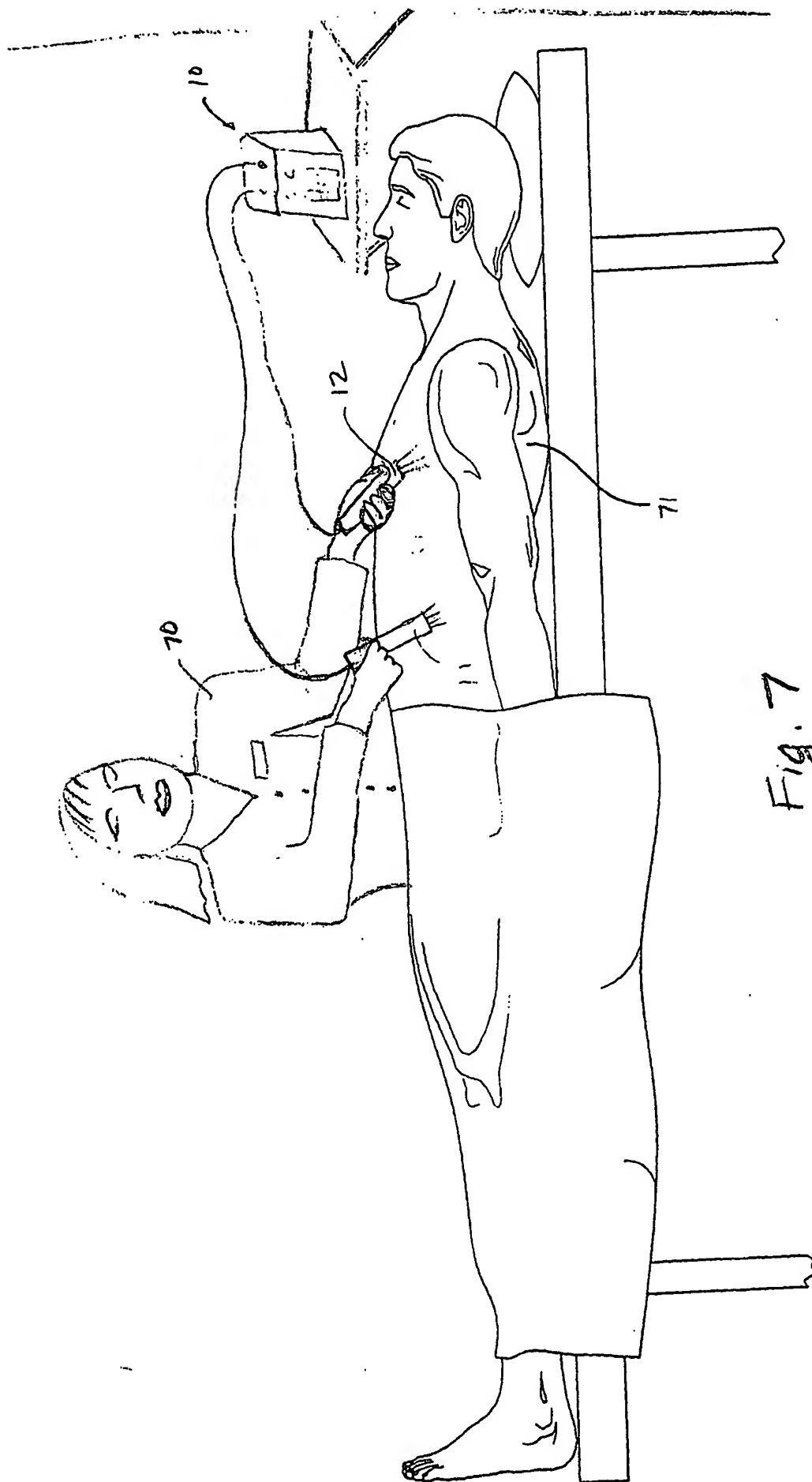


Fig. 7